



VIRUPAKSHA ORGANICS LIMITED UNIT-I

Survey No.10, Gaddapotharam Village, Jinnaram Mandal,
Sangareddy Dist.-502 319, Telangana, INDIA.

CERTIFICATE OF ANALYSIS

Name of the product	FLUCONAZOLE USP		
Batch Number	AFLUC23011	A.R. No.	CB/FLU-2302026
Mfg.Date	02.19.2023	Retest date	02.18.2028
Date of Analysis	26.02.2023		

S. No.	TEST	SPECIFICATION	RESULT
1.	Description	White or almost white, crystalline powder.	White crystalline powder
2.	Solubility	Freely soluble in methanol, soluble in alcohol and in acetone, sparingly soluble in isopropanol and in chloroform, slightly soluble in water, very slightly soluble in toluene.	Complies
3.	Identification a) Infrared absorption	To be concordant with working standard spectrum.	Complies
	b) HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay	Complies
4.	Loss on drying	Not more than 0.5 %	0.19%
5.	Residue on ignition	Not more than 0.1 %	0.05%
6.	Related compounds by HPLC Impurity at RRT 0.6	Not more than 1.0 %	0.12%
	Related compound A	Not more than 0.2 %	0.01%
	Related compound B	Not more than 0.1 %	0.02%
	Related compound C	Not more than 0.2 %	Not detected
	Any individual unspecified impurity	Not more than 0.1 %	0.02%
	Total unknown impurities	Not more than 0.3 %	0.05%
	Total impurities	Not more than 1.5 %	0.20%
7.	Assay by HPLC (on the dried basis)	Not less than 98.0% and Not more than 102.0%	99.9%

	Prepared by	Checked by	Approved by
Signature			
Date	26.02.2023	26.02.2023	26.02.2023
Name	S.Nagarjuna Reddy	Y.Vinod	L.Damodaram
Designation	QC Chemist	Assistant Manager- QC	Deputy Manager- QC

Corporate office: B1&B2, IDA, Gandhinagar, Hyderabad-500 037, Telangana, INDIA.
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8.	Residual solvents by GC(*)		
	Isopropyl alcohol	Not more than 5000 ppm	Not detected
	Methylene dichloride	Not more than 600 ppm	Not detected
	Ethyl acetate	Not more than 5000 ppm	Not detected
9.	Particle size(*)	D ₉₀ - 300±10% microns	293 microns

Remarks: The product meets the requirements of USP and (*) additional specification.

Signature	Prepared by	Checked by	Approved by
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